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COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER ISSAC, ROY P	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/712,703  
Filing Date: November 12, 2003  
Appellant(s): REGIERT ET AL.

\_\_\_\_\_  
ELIZABETH COLLARD RICHTER  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 02/04/08 appealing from the Office action mailed 09/25/07.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Bruzzese et. al.	EP 0470452	2 February 1992
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4,393,043	Britten-Kelly	05-1983
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Schlenk, H. Journal of the American Chemical Society, 83, 2312-2320; 1961.

Wu et. al., The Journal of Nutrition, 72-79, 2001.

Cunnane et. al. Progress in Lipid Research, 42, 544-568, 2003.

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bruzzese et. al. (EP 0470452).

Bruzzese et. al. discloses a method for the production of complexes of long chain polyunsaturated fatty acid with cyclodextrin. (Abstract; Column 3, paragraph 2). Bruzzese et. al. discloses a series of complexes of eicosapentaenoic acid and docosahexaenoic acid, both essential fatty acids, in 1:1, 1:1.25, 1:2 and 1:3 ratios. (Examples 1, 4, 5, 6, 7, 8, 9 and 10; Columns 4-7). Bruzzese further discloses complexes of  $\alpha$ -cyclodextrin with essential fatty acids. (Example 6). The GC analysis of the product made shows an oil content of 26.3% representing a molar ratio of about 1:1 with cyclodextrin. However, there is no indication as to whether complexes of 3:1 or 4:1 ratios were present in the product mixture. No analysis of the complex formed that would definitively indicate the individual complexes formed is disclosed. However, one of ordinary skill in the art would find it very likely that a mixture of complexes with 3:1 or 4:1 formed even in small quantities in such product mixtures. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art

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inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruzzese et. al. (EP 0470452) in view of Schlenk et. al. (J. Am. Chem. Soc., 83, 2312-2320; 1961) further in view of Koulbanis et. al. (U.S. Patent No. 4,393,043).

Bruzzese et. al. discloses a method for the production of complexes of long chain polyunsaturated fatty acid with cyclodextrin. (Abstract; Column 3, paragraph 2). Bruzzese et. al. discloses a series of complexes of eicosapentaenoic acid and docosahexaenoic acid, both essential fatty acids, in 1:1, 1:1.25, 1:2 and 1:3 ratios. (Examples 1, 4, 5, 6, 7, 8, 9 and 10; Columns 4-7). Bruzzese further discloses complexes of  $\alpha$ -cyclodextrin with essential fatty acids. (Example 6). The GC analysis of the product made shows an oil content of 26.3% representing a molar ratio of about 1:1 with cyclodextrin. However, there is no indication as to whether complexes of 3:1 or 4:1 ratios were present in the product mixture. Note that it is considered well within the basic skills of one of ordinary skill in the art to change the amount of ingredients during the preparation of guest-host complexes to prepare complexes of higher order.

Bruzzese et. al. does not expressly disclose a 3:1 or 4:1 complex of alpha cyclodextrin with an essential fatty acid or an emulsion made with said complex.

Schlenk et. al. discloses that fatty acids with 17 and higher carbons produce 1:3 complexes with cyclodextrins. (Page 2317, Column 2, paragraph 3, lines 10-20; Page 2315, Column 1, Figure 4). The figure indicate a relation between fatty acid chain length and the number of cyclodextrins in the complex. (Figure 4, right axis). The figure indicate a preference for alpha cyclodextrin to form higher order complexes. Schlenk et. al. indicates that the presence of cyclodextrins increase the solubility of fatty acids. (Page 2317, Column1, Paragraph 2). Note that most essential fatty acids are of chain lengths 15 and higher.

Koulbanis et. al. discloses the use of vitamin F for the preparation of cosmetics. (Column 1, Paragraph 1). Koulbanis et. al. discloses vitamin F as useful for the treatment of skin dryness. (Column 1, lines 27-30). Koulbanis et. al. further disclose that the use of vitamin F is limited by problems with oxidation. (Column 1, lines 30-35). Koulbanis further discloses several emulsions comprising vitamin F compounds and oil by mixing the ingredients. (Columns 5-6; Examples II-XII). Note that the preparation of a dispersion before the formation of an emulsion is considered a routine step within the capabilities of one skill in the art in the cosmetic art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare complexes of essential fatty acids with cyclodextrins in the 3:1 or higher ratio and to prepare emulsions with them because Burzzese disclose complexes of essential fatty acids with alpha, beta and gamma cyclodextrins and Schlenk et. al. disclose a chain length to complexation ratio in which alpha cyclodextrins

forms higher order complexes, and Koulbanis discloses the use of vitamin F in emulsions of topical compositions.

One of ordinary skill in the art would have been motivated to use alpha cyclodextrins to form complexes with essential fatty acids because the complexation increases solubility and alpha cyclodextrin forms higher order complexes with longer chain fatty acids. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Therefore, one of ordinary skill in the art would have reasonably expected that the use of alpha cyclodextrin with one of the long chain essential fatty acid would have formed a complex of cyclodextrin and essential fatty acid in 3:1 or 4:1 ratio.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

#### **(10) Response to Argument**

Eicosapentaenoic acid and docosahexaenoic acid are considered as essential fatty acids:

The critical question is whether one of ordinary skill in the art would consider either eicosapentaenoic acid or docosahexaenoic acid as essential fatty acids. In response to appellants' arguments submitted after final rejection the examiner has cited two prior art references in which these two compounds were described as essential fatty

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acids. (Wu et. al., *Docosahexaenoic acid is superior to Eicosapentaenoic acid as the essential fatty acid for growth of grouper, *Epinephelus malabaricus**, The Journal of Nutrition, 72-79, 2001; Cunnane et. al., *Problems with essential fatty acids: time for a new paradigm?* Progress in Lipid Research, 42, 544-568, 2003). Wu et. al. teaches that docosahexaenoic acid is superior to eicosapentaenoic acid as essential fatty acid for growth. Since Wu et. al. refers to these two compounds as essential fatty acids, it is

Appellants argue that examiner assumes that a polyunsaturated fatty acid is an essential fatty acid and that such assumption is incorrect. However, the examiner has only stated that both eicosapentaenoic acid and docosahexaenoic acid are essential fatty acids. Bruzesse et. al. teaches the complexation of these two compounds with cyclodextrins. Both eicosapenaenoic acid and docosahexaenoic acid are described in the literature as essential fatty acids. For example, Wu et. al. refers to docosahexaenoic acid and eicosapentaenoic acids as essential fatty acids in the article title. The specification does not define the phrase essential fatty acids or otherwise exclude these two compounds from the definition of essential fatty acids. Appellants' description of omega-6-polyunsaturated fatty acids as preferable essential fatty acid does not provide a clear definition. Since there is no explicit definition given, this term should be given its ordinary meaning and broadest reasonable interpretation. Appellants note that Bruzzese discloses solely polyunsaturated fatty acids. However, one of ordinary skill in the art would consider eicosapenaenoic acid and docosahexaenoic acid as essential fatty acids as evidenced by the cited references.

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One of ordinary skill in the art would expect cyclodextrins and long chain fatty acids to form complexes with three or more cyclodextrins:

Appellants argue that it is unjustified to require the applicants to show a novel or unobvious difference between the claimed product and the product of the prior art. Bruzzese et. al. does not expressly disclose a 3:1 or 4:1 complex of alpha cyclodextrin with an essential fatty acid. However, one of ordinary skill in the art would expect mixtures of long chain essential fatty acids and cyclodextrins to have 3:1 and 4:1 complexes along with the more common 2:1 complexes. Generally, cyclodextrins are cyclic structures with an inner hydrophobic cavity. They can stack one on top of the other to create longer cavities in which hydrophobic molecules can sit. Schlenk et. al. teaches the relationship between the length of hydrophobic chains and the number of cyclodextrins that will stack to accommodate such length. Schlenk et. al. teaches that fatty acids with 17 and higher carbons produce 1:3 complexes with cyclodextrins. Eicosapentaenoic acid and docosahexaenoic acid have carbons chains of 20 and 22 carbons respectively. As such, one of ordinary skill in the art would view a composition comprising either of these two compounds and cyclodextrins to produce a mixture that includes 3:1 complexes. Applicants' further argue that the aim of the present invention, stability, is different from that the solubility consideration of Schlenk et. al. However, the fact that Appellants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

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The poor stability of essential fatty acids and the improved stability with cyclodextrin complexation is well known by one of ordinary skill in the art:

Appellants further argue that Koulbanis only identifies the problem of state of the art in the use of essential fatty acids in (vitamin F) in cosmetics, which the instant application solves. The problem in the state of the art is the oxidation of fatty acids. Appellants note that none of the cited references suggest that a complex of alpha cyclodextrin with an essential fatty acid would solve these problems. However, Bruzzese notes in reference to polyunsaturated fatty acids, of which essential fatty acids is a subgroup that they are "easily oxidized in the air owing to the large number of carbon-carbon double bonds in their molecules". (See Column 1, lines 30-35). Bruzzese further teaches that, "To forestall these disadvantages U.S. Patent No. 4,438,106 describes inclusion compounds of eicosapentaenoic acid (EHA) and docosahexaenoic acid (DHA), their alkaline salts and alkyl esters in cyclodextrin..." (See Column 1, lines 51-55). The problem of oxidation of essential fatty acids due to the presence of multiple double bonds is well known in the prior art. Furthermore, the solution of complexing essential fatty acids with cyclodextrin to improve stability is also well known in the prior art.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Roy P Issac/

Examiner, Art Unit 1623

Conferees:

/Elli Peselev/

Primary Examiner, Art Unit 1623

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623